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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,800	07/18/2003	Roman Turovskiy	H-US-00497	3485

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UNITED STATES SURGICAL,
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EXAMINER

VRETTAKOS, PETER J

ART UNIT PAPER NUMBER

3739

DATE MAILED: 10/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/622,800

Applicant(s)

TUROVSKIY ET AL.

Examiner

Peter J. Vrettakos

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) 25-78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The application is published application number: 2005/0015081.

This action is final as necessitated by amendment.

Pending claims are 1-78. Claims 25-78 are withdrawn. **Claims 1-24 are rejected.** Claim 1 is independent.

Rudie et al. (6,496,737) is inserted into all prior rejections to address newest amendments. Rudie et al. (6,496,737) discloses a microwave antenna (lumen 70) in direct connection with cooling fluid (fluid lumen 78-80) that is encapsulated by a cooling jacket (32). See col. 6:52-54 and figure 5.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16 and 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Storm (4,140,130) in view of Edwards (5,964,755) and further in view of Gough et al. (5,951,547) and even further in view of Rudie et al. (6,496,737).

Storm neglects to expressly mention a tissue penetrating microwave antenna.

Storm/Edwards neglects to expressly mention a percutaneously penetrating microwave antenna.

Edwards discloses an introducer (14) for use with a microwave antenna (patented claim 15). The expandable member 12 is analogous to Storm's "cooling jacket". This disclosure is also construed as a tissue penetrating microwave antenna (patented claim 15, energy delivery device – 10 in figure 1a; element 14 can be designated as being part of the microwave antenna). In other words, element 14 (an introducer) being part of the microwave antenna (energy delivery device 10 – patented claim 15) means that element 10 is capable of tissue penetration (see col. 4:19-23). The Examiner asserts that tissue penetration includes entry into body lumens such as the cervix.

Gough discloses a percutaneously advanceable microwave antenna (col. 5:64-67).

Rudie et al. (6,496,737) discloses a microwave antenna (lumen 70) in direct connection (permitting a direct cooling effect on the antenna – motivation) with cooling fluid (fluid lumen 78-80) that is encapsulated by a cooling jacket (32). See col. 6:52-54 and figure 5.

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Storm in view of Edwards and further in view of Gough and even further in view of Rudie by including a percutaneous introducer for use with a microwave antenna. The motivation would be to provide a means

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to percutaneously place a penetrating microwave antenna such as that in Edwards and Gough combined, while retaining the cooling abilities of the Storm device. In other words, it would have been obvious at the time of the invention to integrate the tissue penetrating antenna in Edwards and Gough into the Storm cooling jacket antenna assembly. The motivation would be to increase the applicability of the Storm cooling jacket antenna assembly from external applications to internal applications. This is no great cognitive leap because the Storm patent actually addresses treatment of internal tissue (with tumor – 14 – see figure 1).

Note: the remainder of the rejection includes Storm exclusively.

Independent claim 1

Storm discloses a cooling system for use with a microwave antenna (col. 2:28-32; col. 7:49-53; 12, figure 2; note that element 40 in figure 9 is an analogue of element 12), comprising:

a cooling jacket (30, col. 10:2-6, another analogue is the structure enveloping chamber 61) adapted to at least partially surround a microwave antenna, wherein the cooling jacket is further adapted to circulate (**Rudie et al. figure 5**) a cooling fluid (26a, figure 6) through the fluid channel (**Rudie et al. figure 5**) such that at least a portion of the microwave antenna is in fluid contact with the cooling fluid (col. 10:9-13).

Dependent claims (parentheticals refer to Storm)

2. The system of claim 1 further comprising at least one inlet lumen (59) and at least one outlet lumen (60) each in fluid communication with the cooling jacket for circulating the cooling fluid therethrough.
3. The system of claim 2 wherein a distal end of the inlet lumen (59) is positioned near or at a distal end (43) of the microwave antenna (depicted in figure 9).
4. The system of claim 2 wherein a distal end of the outlet lumen (60) is positioned proximally (slightly) of the microwave antenna distal end (43) as depicted in figure 9.
5. The system of claim 2 wherein the inlet lumen (59) is defined along an outer surface (figure 9 shows that element 59 is connected but separate from the cooling jacket which envelops chamber 61) of the cooling jacket (structure that envelops chamber 61 in figure 9).
6. The system of claim 2 wherein the inlet lumen (59) is defined within a wall (figure 9 shows that element 59 is connected within a wall to the cooling jacket permitting inflow of cooling fluid) of the cooling jacket (depicted in figure 6 – shows the device's distal cross-section).

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7. The system of claim 1 further comprising a tip (53, dielectric wall, figure 9) at a distal end of the cooling jacket (envelops chamber 44 in figure 9).

8. The system of claim 7 wherein the tip is tapered (element 53 "tip" is curved and therefore can be characterized as "tapered" in the context depicted in figure 9).

9. The system of claim 7 further comprising a power generator (18, figure 1) in electrical communication with the tip.

10. The system of claim 7 wherein a distal end of the microwave antenna (12/40) is securable (col. 11:13-17, elements 55 and 56 in figure 9) to a proximal portion of the tip (53).

11. The system of claim 10 wherein the tip (53) is adapted to be in electrical communication with the distal end (51) of the microwave antenna. Figure 9 shows that elements 51 and 53 overlap and are consequently in electrical communication at the distal most point of the device depicted.

12. The system of claim 1 further comprising a handle assembly (see the valve in figure 1 attached to the tubular element 28) for attachment to a proximal end (tubular element 28 extends to element 26/59 which contacts the proximal wall of the cooling jacket) of the cooling jacket.

13. The system of claim 12 wherein the handle assembly defines (inherent to the design of a flow control valve) at least one lumen therethrough which is in fluid communication (through element 28) with the cooling jacket.

14. The system of claim 1 further comprising a pump (col. 6:60-65) for circulating the cooling fluid through the cooling jacket.

15. The system of claim 1 wherein the cooling fluid comprises a liquid, gas, or combination thereof (again, see col. 6:60-65).

16. The system of claim 15 wherein the liquid comprises water or saline (col. 6:52-58).

20. The system of claim 1 wherein the cooling jacket is configured in length (the cooling jacket which envelops chamber 61 in figure 9 is the same length as element 43) to match a radiating portion (43) of the microwave antenna. Length is defined here as the distance along the device's longitudinal axis.

21. The system of claim 1 wherein the cooling jacket defines at least a first (44) and a second region (61) adjacent to and separate from one another, the first region being adapted to retain the cooling fluid from a first source (26a in figure 6) in fluid contact with a first portion (inside of element/wall 43) of the microwave

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antenna, and the second region being adapted to retain cooling fluid from a second source (36a in figure 6) in fluid contact with a second portion (outside of element/wall 43) of the microwave antenna.

22. The system of claim 21 wherein the cooling fluid from the first source is maintained at a first temperature and the cooling fluid from the second source is maintained at a second temperature. Note: because the sources (26a and 36a) are separate it is inherent that they could be maintained at different temperatures. Also see col. 10:12-15.

23. The system of claim 21 wherein the cooling jacket defines a plurality of additional regions (44, 61) adjacent to and separate from one another. Also see figures 11,13,14 which show numerous cooling jackets (74).

24. The system of claim 1 wherein the cooling jacket defines at least a first (44) and a second (61) region adjacent to and separate from one another, the first region (44) being adapted to retain the cooling fluid from a first source (26a) in fluid contact (see figure 9) with a first portion (inside of wall 43) of the microwave antenna, and the second region (61) being adapted to retain cooling fluid from the first source (see next sentence) in fluid contact with a second portion (outside of wall 43) of the microwave antenna. Storm discloses that the separate regions of cooling fluid may come from the same source in the disclosure found in col.

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10:9-13, specifically, "may be the same as that circulated through electrode means[.]"

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Storm in view of Edwards (5,964,755) and further in view of Gough et al. (5,951,547) and even further in view of Uthe (5,829,519) and even further in view of Rudie et al. (6,496,737).

Storm/Edwards/Gough/Rudie neglect to expressly mention the materials used in the design of their invention's tubular members.

Uthe discloses a microwave antenna (the use of the antenna is not relevant to this rejection) suggestively made up of ceramics, polymers, metals, as well as a temperature sensor (patented claim 12 and col. 3:35-40).

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Storm in view of Edwards (5,964,755) and further in view of Gough et al. (5,951,547) and even further in view of Uthe and even further in view of Rudie by including a temperature sensor as well as choosing from different materials to comprise the device. The motivation would be to provide temperature feedback to the user, as well as choices of commonly known material types, which could make an effective microwave antenna.

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Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Storm in view of Edwards (5,964,755) and further in view of Gough et al. (5,951,547) and even further in view of Edwards et al. (5,281,217) and even further in view of Rudie et al. (6,496,737).

Storm/Edwards ('755)/Gough/Rudie neglects to expressly mention carbon dioxide use for cooling purposes in a microwave antenna.

Edwards discloses carbon dioxide use for cooling purposes in a microwave antenna.

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Storm in view of Edwards (5,964,755) and further in view of Gough et al. (5,951,547) and even further in view of Edwards and even further in view of Rudie by including carbon dioxide as a means to cool. The motivation would be to provide a well-known choice of cooling gas in microwave antennas.

Double Patenting

The **nonstatutory** double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed.

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Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed **terminal disclaimer** in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-45 and 64-77 of **co-pending Application No. 11/053,987**. Although the conflicting claims are not identical, they are not patentably distinct from each other because both groups of claims disclose a microwave antenna assembly with cooling system.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

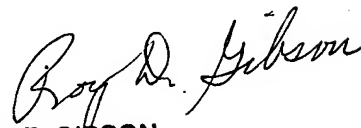
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos
October 24, 2006



ROY D. GIBSON
PRIMARY EXAMINER